UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re BAYCOL PRODUCTS LITIGATION	:	MDL No. 1431 (MJD)
This Document Relates to:	:	
All Actions	:	

INTRODUCTION TO BAYER AND GSK'S MOTIONS TO EXCLUDE CERTAIN EXPERT WITNESS TESTIMONY and MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE EXPERT TESTIMONY BASED ON ADVERSE EVENT REPORTS

The PSC has proffered the testimony of 14 generic experts in this MDL; 13 of them are subject to *Daubert* motions today being filed by Bayer and GSK. Each of these witnesses seeks to present supposedly "scientific" testimony that is nothing of the sort.

As Justice Blackmun wrote in *Daubert*, scientific testimony is admissible only if it is based on "scientific knowledge" "derived by the scientific method":

> Proposed testimony must be supported by appropriate validation – ***i.e., "good grounds," based on what is known***. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.

Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 590 (1993) (emphasis added).

The PSC's experts do not have "good grounds" for the opinions offered here. Rather, these experts have disregarded the scientific method in preparing their opinions, and resorted to outcome-oriented reasoning and speculation. Several themes recur in their proposed testimony:

1. Many PSC experts opine that Baycol was more dangerous or more toxic than other statins. These opinions are based primarily on adverse event reports, articles purportedly mentioning adverse event reports, and an analysis of adverse event reports prepared by one of the PSC's testifying experts.

However, the FDA has explicitly and emphatically stated that adverse event reports have not been scientifically verified and therefore cannot be used to calculate incidence or estimates of drug risk. FDA Office of Postmarketing Drug Risk Assessment, "Adverse Event Reporting System (AERS): Brief Description with Caveats of System" (Oct. 18, 1999) (Ex. A) at 2. ***Because AERs are not the sort of evidence upon which scientists properly rely in drawing conclusions about comparative drug risk, the PSC cannot carry its burden of proving that its experts should be allowed to offer such testimony here.*** *Daubert*, 509 U.S. at 592 (proponent of expert testimony must prove its relevance and reliability); *id*. at 595 (the "focus, of course, must be on principles and methodology, not on the conclusions that they generate"); *DeLuca v. Merrell Dow Pharms., Inc.*, 791 F. Supp. 1042, 1051 (D.N.J. 1992) (rejecting AERs as "not of a type of data that are reasonably relied upon by experts in the field of epidemiology").

2. Several PSC experts opine that Baycol caused muscle injury that lingered long after patients had stopped taking the medicine or contend that alleged Baycol induced-injury can be diagnosed after-the-fact, in the absence of objective tests at the time of Baycol usage supporting the diagnosis. These proposed witnesses base their opinions on interpretations of articles that say nothing of the sort, animal studies, and wholly unrelated data – such as the length of time it takes a muscle to recover after space travel or after a muscle has been cut in surgery. ***This proposed testimony is based on subjective belief and unsupported speculation and must therefore be excluded.*** Fed. R. Evid. 702; *Daubert*, 509 U.S. at 590; *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("Nothing in *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert"); *Sorensen v. Shaklee Corp.*, 31 F.3d 638, 649 (8th Cir. 1994).

3. Some of the PSC's experts also opine that defendants acted unethically with respect to the development, FDA approval, marketing and withdrawal of Baycol. ***Such opinions cannot be tested empirically and therefore are not the stuff of science; they are advocacy – in some instances, advocacy of positions preempted by federal law – and therefore should be excluded.*** *Daubert*, 509 U.S. at 593-94; *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350-53 (2001) (alleged breach of company's duties to FDA cannot form a basis for liability under state law); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (opinions "on the intent, motives or states of mind of corporations . . . have no basis in any relevant body of knowledge or expertise").

Defendants have filed a motion as to each of the generic expert witnesses whose testimony they seek to exclude, in whole or in part. Defendants also have filed two "umbrella" motions: one directed to the PSC's penchant for having one testifying expert rely on another testifying expert (*see Dura Automotive Systems of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002) ("A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty")); and the brief that immediately follows, addressed to the misuse of AERs. To assist the Court in keeping track of these and other issues addressed in these briefs, defendants have prepared and filed a summary chart that identifies the testimony that they seek to exclude as to each expert.

THIS COURT SHOULD EXCLUDE COMPARATIVE RISK TESTIMONY BASED UPON ADVERSE EVENT REPORTS

Every pharmaceutical manufacturer receives information from various sources about adverse events that patients reportedly experienced while taking the manufacturer's medicine. For example, subsequent to the marketing of Baycol, Bayer received reports that patients taking Baycol had experienced rhabdomyolysis ("rhabdo"), particularly when the medicine was used with gemfibrozil ("combination therapy"). In accordance with regulations of the Food and Drug Administration ("FDA"), Bayer reported these "adverse drug experience[s]" to the FDA in periodic reports called adverse event reports ("AERs"). *See* 21 C.F.R. § 314.80(c). The FDA collects AERs such as these as part of its post-marketing observation of prescription medicines.

Although AERs are useful for some purposes, the FDA has made clear that AER data cannot be used to calculate estimates of drug risks, and cannot be used to make comparisons of different medications. *See* FDA Caveats (Ex. A) at 2. There are good reasons for this. For instance:

- The information contained in AERs has not been scientifically verified;
- The medicine at issue may have nothing to do with the reported reaction; and
- AER data have inherent biases that render any comparative analysis of AERs unreliable for determining estimates of drug risk.

For these reasons and others, the scientific community agrees with the FDA that analysis of AERs is not a valid method of determining the incidence rates or relative risks of medicines. And, courts likewise have excluded expert testimony based on AER data.[1]

Many of the PSC's generic experts, however, have done precisely what cannot validly be done: they have opined that Baycol caused a higher rate of muscle toxicity based upon an analysis of the number of AERs filed about Baycol compared to

[1] *See Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1165 (S.D. Fla. 1996) ("The FDA has confirmed that the [AER] information cannot be used to estimate the inciden[ce] of adverse drug reactions, or for comparisons of drug safety"), *aff'd*, 158 F.3d 588 (11th Cir. 1998); *see also DeLuca v. Merrell Dow Pharms., Inc.*, 791 F. Supp. 1042, 105 (D.N.J. 1992) (noting AERs "have inherent biases as they are second-or-third hand reports, are affected by medical or mass media attention, and are subject to other distortions").

other statins.[2] Such testimony should be excluded because it is not based on a reliable scientific methodology.

BACKGROUND

Several of the PSC's generic experts have relied upon AER data to render opinions about the safety of Baycol compared to other statins. While their language varies, all of this testimony boils down to the same opinion: that Baycol caused a higher rate of muscle toxicity, based upon an analysis of the number of AERs filed about Baycol compared to other statins. For example:

- **Harland Austin, D.Sci. (epidemiology/biostatistics)**: Dr. Austin uses comparative AER analysis to support the opinion that monotherapy Baycol (*i.e.*, Baycol prescribed alone for cholesterol management) increases the risk of myopathy [as compared with other statins], *see* Austin Rep. (Ex. B) ¶ 17;

[2] *See, e.g.*, Report of Harland Austin (Ex. B) ¶ 17; Deposition of Charles E. Boult (Ex. C) at 46, 95-96, 182, 294; Report of Bruce Carlson (Ex. D) ¶ 8; Report of John W. Farquhar (Ex. E) ¶¶ 30, 56-99; Report of Richard Kapit (Ex. F) ¶¶ 72-75, 84, 113-32; Report of R. Samuel Mayer (Ex. G) ¶¶ 11, 16; Report of Stephen Raskin (Ex. H) ¶¶ 6, 12, 14, 15, 17, 23; Deposition of David Richman (Ex. I) at 133-37; Report of Martyn Smith (Ex. J) ¶¶ 8, 9, 11; Deposition of Martyn Smith (Ex. K) at 130-34; Deposition of Paul David Stolley (Ex. L) at 72-73, 223, 299, 363, 379; Report of Thomas Zizic (Ex. M) ¶¶ 17, 46, 63; Deposition of Thomas Zizic (Ex. N) at 144.

- **Charles Boult, M.D. (geriatrics):** Dr. Boult opines that Baycol exposed patients to a higher risk of adverse effects than other statins, based on an article that relies upon AER data; *see* Boult Dep. (Ex. C) at 46, 95-96, 182, 294;
- **Bruce Carlson, M.D. (muscle regeneration; embryology; gerontology)**: Dr. Carlson opines that Baycol has a higher incidence of myopathy and death than other statins based on AER data, *see* Carlson Rep. (Ex. D) ¶ 8;
- **John Farquhar, M.D. (epidemiology; cardiology)**: Dr. Farquhar compares AERs between statins to conclude that Baycol caused significantly greater muscle disease – both rhabdomyolysis and myalgia – than other statins, *see* Farquhar Rep. (Ex. E) ¶ 30, 56-99;
- **Richard Kapit, M.D. (FDA)**: Dr. Kapit relies upon AERs to support his opinion that Baycol had a higher incidence of damage to muscle tissue than other statins, *see* Kapit Rep. (Ex. F) ¶¶ 72-75, 84, 113-32;
- **R. Samuel Mayer, M.D. (physical medicine/rehabilitation)**: Dr. Mayer relies upon comparative AER analysis done by others to support his opinion that Baycol was associated with greater frequency and severity of muscle damage than other statins, *see* Mayer Rep. (Ex. G) ¶¶ 11, 16;

- **Stephen Raskin, M.D. (cardiology)**: Dr. Raskin proposes to tell the jury that "Bayer failed to disclose to the medical community important information about the risk of muscle injuries associated with the use of Baycol," but concedes that this opinion was based only upon AERs, *see* Raskin Rep. (Ex. H) at ¶¶ 6, 12; *see also id.* ¶¶ 14, 15, 17, 23, 21, 25;
- **David Richman, M.D. (neurology)**: Dr. Richman relies on comparative AER analysis to support his opinion that Baycol had a higher rate of myopathy than other statins, *see* Richman Dep. (Ex. I) at 133-37;
- **Martyn Smith, Ph.D. (toxicology)**: Dr. Smith relies on comparative AER data to support his opinion that Baycol is more toxic than any other statin, *see* Smith Rep. (Ex. J) ¶¶ 8, 9, 11; Smith Dep. (Ex. K) at 130-34;
- **Paul David Stolley, M.D. (internal medicine)**: Dr. Stolley testified that "monotherapy with Baycol is more dangerous than monotherapy with alternative statins" based almost entirely upon a report issued by the European Medicines Agency ("EMEA"), and particularly upon the adverse event reporting data summarized in it, *see* Stolley Dep. (Ex. L) at 72-73, 223, 299, 363, 379; and

- **Thomas Zizic, M.D. (rheumatology)**: Dr. Zizic also relies on comparative AER analysis to support his opinion that Baycol is more toxic than any other statin, *see* Zizic Rep. (Ex. M) ¶¶ 17, 46, 63; Zizic Dep. (Ex. N) at 144.

All such expert testimony is inadmissible, as explained below.

ARGUMENT

As the Supreme Court ruled in *Daubert*, federal courts are required to screen proffered expert testimony for relevance and reliability. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); Fed. R. Evid. 702. The proponent of expert testimony must prove its admissibility by a preponderance of evidence. *See Daubert*, 509 U.S. at 592; *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). In order to be admissible, expert testimony must be based upon sufficient facts or data and must be the product of reliable principles and methods, and the witness must apply those principles and methods reliably to the facts of the case. Fed. R. Evid. 702; *Lauzon*, 270 F.3d at 686. A district court's gatekeeping function "separates expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge." *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001).

The FDA and scientific community agree that AER data do not constitute "good grounds" upon which comparisons between different medications can be made. As a result, courts have excluded expert testimony based on AER data. The same conclusion should be reached here: expert testimony that Baycol caused a higher rate of muscle toxicity, based upon comparative AER analysis, is inadmissible because it is not based upon a reliable scientific methodology.

I. THE FDA HAS CONCLUDED THAT ADVERSE EVENT REPORTS ERS DO NOT CONSTITUTE A RELIABLE BASIS TO MAKE COMPARISONS BETWEEN DIFFERENT MEDICATIONS.

AERs are anecdotal reports that doctors, patients, pharmacists, competing sales representatives, and even plaintiffs' lawyers (via the filing of lawsuits) submit to pharmaceutical companies, asserting that someone experienced some undesired symptom while taking the company's medicine. *See* 21 C.F.R. § 314.80(c); *see also* Stolley Dep. (Ex. L) at 214. Pharmaceutical companies must report "[a]ny adverse event associated with the use of a drug in humans, ***whether or not considered drug related.***" 21 C.F.R. § 314.80(a) (emphasis added).

There is no causation filter attached to these reports. As the FDA has explained, "physicians and consumers are encouraged to report all suspected ADEs [adverse drug events], not just those that are already known to be caused by the drug. The adverse event may . . . have occurred by chance at the same time the suspect drug was administered." Annual Adverse Drug Experience Report: 1996, Surveillance and Data Processing Branch, Division of Pharmacovigilance and Epidemiology, Office of Epidemiology and Biostatistics, Center for Drug Evaluation and Research, Food and

Drug Administration (Oct. 30, 1997) ("1997 FDA Report") (Ex. O) at 1. As a result, the existence of an AER "does not necessarily reflect a conclusion . . . that the report or information constitutes an admission that the drug caused or contributed to an adverse effect." 21 C.F.R. § 314.80(k).

The FDA's AER database – known as the Medwatch system – can be a tool for generating "signals" for the FDA and manufacturers that a medicine may be associated with a particular (and often previously unrecognized) adverse reaction. *See* Strom Rep. (Ex. P) ¶ 7. When such a signal is identified, the appropriate response is for the manufacturer to investigate further by undertaking a formal well-designed study, which is usually epidemiologic in nature.[3] *Id*.; *see also* Austin Rep. (Ex. B) ¶ 26 ("Many epidemiologists argue that spontaneous reports can provide only a 'signal' of a problem and must be confirmed by a more controlled study.").

The FDA's AER database, however, cannot be used to determine the incidence rate of a particular adverse event associated with a medicine, or to compare incidence rates or drug risk between different medicines. The FDA division responsible

[3] In fact, that is exactly what occurred here: Bayer launched the PacifiCare cohort epidemiologic study to evaluate the signal raised by AERs involving rhabdo in Baycol users. Strom Rep. (Ex. P) ¶¶ 11, 13; *accord* Austin Rep. (Ex. B) ¶¶ 13-14 (acknowledging that PacifiCare was undertaken by Bayer as a follow-up to AERs involving rhabdo with Baycol use); Stolley Rep. (Ex. Q) ¶ 14 (same). The PSC's expert, Dr. Austin, acknowledged it was an "appropriate response" for Bayer to undertake. Austin Dep. (Ex. R) at 187-88.

for collecting and monitoring AERs provides the following detailed cautions to all persons reviewing AERs:

> CAVEATS:
>
> There are some important things to remember when reviewing or analyzing data from AERs.
>
> 1. Reports contain only those reactions voluntarily submitted either directly to the FDA or to the drug manufacturer by consumers and/or members of the health profession . . . .
>
> 2. The information contained in the reports ***has not been scientifically or otherwise verified.***
>
> 3. For any given report, ***there is no certainty that the suspected drug caused the reaction.*** This is because physicians are encouraged to report suspected reactions. The event may have been related to the underlying disease for which the drug was given to concurrent drugs being taken or may have occurred by chance at the same time the suspected drug was taken.
>
> 4. Accumulated case reports ***cannot be used to calculate incidence or estimates of drug risk.***
>
> 5. Numbers from these data must be carefully interpreted as reporting rates and not occurrence rates. ***True incidence rates cannot be determined from this database. Comparisons of drugs cannot be made from these data.***

FDA Caveats (Ex. A) at 2 (emphasis added).

II. THE SCIENTIFIC COMMUNITY HAS CONCLUDED THAT AERs DO NOT CONSTITUTE A RELIABLE BASIS TO MAKE COMPARISONS BETWEEN DIFFERENT MEDICATIONS.

Medical and scientific experts agree with the FDA that, although AERs have certain useful purposes, they cannot validly be used as proof of relative risk between

medications. In particular, Dr. Janet Arrowsmith-Lowe[4] confirms that "the comparison of reporting rates calculated from spontaneously reported adverse drug events is not generally accepted by the scientific and medical community as a valid methodology for estimating the relative risks of those events associated with individual drug products." Arrowsmith-Lowe Rep. (Ex. S) at 5.

Similarly, Dr. Brian Strom[5] explains that "[b]ecause the FDA's Medwatch system does not provide a reliable scientific basis for determining the incidence rate of a particular adverse event in association with use of a particular drug, the Medwatch system cannot be used to make scientifically valid comparisons of incidence rates between different pharmaceutical products." Strom Rep. (Ex. P) ¶ 6 (emphasis added); *accord* Austin Rep. (Ex. B) ¶ 76 (agreeing with Dr. Strom). *See generally* *Pharmacoepidemiology* 116-19 (Strom ed.) (4th ed. 2005) (Chapter 8, "A View From

[4] Dr. Arrowsmith-Lowe is a board-certified internal medicine doctor, former medical review officer and staff epidemiologist at the FDA, and former epidemic intelligence officer at the National Centers for Disease Control and Disease Prevention.

[5] Dr. Brian Strom is a medical doctor licensed to practice in California and Pennsylvania. He is a Professor of Public Health and Preventive Medicine, Professor and Chair of the Department of Biostatistics and Epidemiology, Professor of Medicine, and Professor of Pharmacology — all at the University of Pennsylvania School of Medicine. He is also the Director for Clinical Epidemiology and Biostatistics at the University of Pennsylvania School of Medicine. He is editor of a leading pharmacoepidemiologic text, *Pharmacoepidemiology*, which includes multiple chapters on the use and interpretation of AERs.

Regulatory Agencies") (discussing spontaneous reports, their weaknesses, and how they should be analyzed).[6]

Indeed, the PSC's own expert, Dr. Austin, concedes that the FDA's AER database cannot be used to estimate drug risk. *See* Austin Dep. (Ex. R) at 52. Rather, "to be scientifically reliable, comparisons between products must be made on the basis of formal scientific studies with control groups." Strom Rep. (Ex. P) ¶ 6.

One of the reasons the medical and scientific communities have rejected comparative AER analysis as a reliable method for determining the relative risk of medicines is that AERs have many inherent biases.[7] Bias is any systematic error in an epidemiology study that results in an incorrect estimate of the association between exposure and risk of disease. *See* Scientific Evidence Manual at 363. For instance, with respect to AERs, there is an increased rate of reporting associated with the "newness" of

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[6] The PSC's own expert, Dr. Farquhar, recognizes Dr. Strom's text as authoritative. *See* Farquhar Dep., Ex. T at 152-153 (relying on "Strom's book" regarding AERs); *id.* at 196 (acknowledging "[i]t's remarkable how much experience he [Dr. Strom] has with AERs").

[7] *See* Arrowsmith-Lowe Rep. (Ex. S) at 5 ("the biases affecting AERs preclude their use in calculating rates of events or in comparing rates of adverse events among pharmaceutical products"); Strom Rep. (Ex. P) ¶ 10 ("Numerous factors are recognized as influencing the reporting rates of adverse events including, but not limited to, the recency of the pharmaceutical products introduction to the market, publicity and/or communications with the medical community about the product and its potential adverse events, and variability in coding and diagnostic definitions with respect to the adverse event reported"); *Pharmcoepidemiology*, *supra*, at 167, 169, Chapter 10 "Spontaneous Reporting in the United States" ("the major limitations of the FDA's AE[R] reporting system reflect the fact that the data are generated in an uncontrolled and incomplete manner" and contain numerous "difficulties with AE[R] recognition, underreporting, biases, estimation of population exposure, and report quality").

a medicine, *i.e.*, how recently it was first introduced on the market. Austin Dep. (Ex. R) at 37, 42; *accord* Stolley Dep. (Ex. L) at 212, 323-27 (acknowledging that it is often found, during first two years of marketing, drugs have a higher reporting rate than during other periods of time). Further, a healthcare provider or patient is more likely to make a voluntary report about an adverse event associated with a medicine about which there has been a lot of publicity — which is referred to as "publicity bias." Austin Dep. (Ex. R) at 37-38; *accord* Stolley Dep. (Ex. L) at 212.

The PSC's expert, Dr. Austin, acknowledges that due to such inherent biases in AER data, you could have two medicines in the same drug class whose association with a particular disease is the same, but the AER reporting rates of the medicines nonetheless differs. Austin Dep. (Ex. R) at 37-40. Further, another of the PSC's experts, Dr. Stolley, testified that because biases or defects in adverse event reporting can vary considerable even among drugs of the same class, voluntary systems of adverse event reporting are of limited use for comparing the relative effects of different drugs. Stolley Dep. (Ex. K) at 324-27.

A problem with using AER data to reach conclusions about the relative safety of medications was illustrated in a recent study: Pierfitte et al., "Is reporting rate a good predictor of risks associated with drugs?" *Br. J. Clin. Pharmacol*. 1999;47:329-31 (Ex. U). Researchers compared reporting rates between six pairs of drugs. The two drugs in each pair had the exact same active ingredient, same recommended dose, same presentation, same approved indications, same launch date, and were launched in the

same country. In other words, the two drugs in each pair, for all intents and purposes, were identical.

Even though the drugs were identical, AER data showed statistically significant differences in reporting rates among these identical drugs in two of these six pairs, or 33 percent of the time. One of the identical drug pairs that showed a statistically significant difference was a pair of statins. The Pierfette study demonstrates what the FDA has told us repeatedly: using comparative AER analysis is an inherently unreliable method for comparing drug safety and does not provide a reliable scientific basis for conclusions about the relative toxicity of different medications.

III. COURTS HAVE EXCLUDED EXPERT TESTIMONY ON DEFECT AND CAUSATION WHERE SUCH TESTIMONY IS BASED UPON AER DATA.

Courts consistently reject expert testimony based on AER analysis. For example, in *McClain v. Metabolife Int'l Inc.*, the Eleventh Circuit reversed a jury verdict where the expert's testimony was based on AERs and other unreliable evidence. 401 F.3d. 1233, 1250 (11th Cir. 2005). The court explained that AERs "reflect complaints called in by product consumers without any medical controls or scientific assessment" and constitute "one of the least reliable sources to justify opinions about both general and individual causation." *Id.*

Similarly, in *DeLuca v. Merrell Dow Pharms., Inc.*, 791 F. Supp. 1042 (D.N.J. 1992), the district court granted summary judgment in favor of Merrell Dow where plaintiff's expert had relied upon AER data to reach conclusions with respect to causation. In doing so, the court noted that AERs "are not of a type of data that are

reasonably relied upon by experts in the fields of epidemiology" for determining causation. *Id*. at 1051. *See also Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 1153, 1156 (D. Mont. 1999) (AERs "are temporal associations between a drug's administration and an unexpected physical reaction" which have "been rejected as reliable scientific evidence").[8]

In sum, the FDA and relevant medical and scientific communities have soundly rejected the use of AER data to assess the comparative safety of different medicines. Courts likewise have excluded expert testimony on defect and causation where such testimony is based on AER data.[9]

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[8] *See also Nelson v. American Home Prods. Corp.*, 92 F. Supp. 2d 954, 969 (W.D. Mo. 2000) (an AER "may be sufficient for formulation of a hypothesis that can later be tested and confirmed, but it is not proof of causation in the courtroom or the scientific community");*Thomas* v. *Hoffman-LaRoche, Inc.*, 731 F. Supp. 224 (N.D. Miss. 1989) (rejecting a doctor's opinion based in part on adverse experience reports), *aff'd*, 949 F.2d 806 (5th Cir. 1992); *Hagaman* v. *Merrell Dow Pharm., Inc.*, Civ. A. No. 84-2202-S, 1987 WL 342949, at *8 (D. Kan. June 26, 1987) (explaining that AERs are often incomplete, in that they often do not indicate whether other drugs are being taken or whether other drugs might have caused the reported health problem).

[9] The PSC's experts cannot get around these well-settled principles by cloaking their AER analysis in a failure-to-warn opinion, *i.e.*, testifying that Bayer should have warned physicians about the results of AER comparisons between Baycol and other statins. *See* Carlson Rep. (Ex. D) ¶ 14; Boult Dep. (Ex. C) at 104; Raskin Rep. (Ex. H) ¶¶ 14, 15, 17, 23. For reasons that will be thoroughly addressed in subsequent briefing, Plaintiffs are precluded from pursuing a claim that Bayer should have warned physicians about a comparison of the number and rate of AERs for Baycol compared with other statins, based on the doctrine of conflict preemption. Given that such a claim is preempted, any expert testimony on the issue is inadmissible under Fed. R. Evid. 702 as it will not assist the jury to determine a fact in issue. Additional reasons why such testimony is admissible are set forth in the *Daubert* motions directed to Drs. Boult, Carlson and Raskin.

Accordingly, expert testimony that Baycol caused a higher rate of muscle toxicity based upon comparative AER analysis is not the product of reliable principles and methods, such as formal scientific studies with control groups. As a result, plaintiffs' cannot bear their burden of proving the admissibility of such testimony. Thus, all such expert testimony is inadmissible under *Daubert* and Fed. R. Evid. 702.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court grant their motion to exclude expert testimony based on AERs.

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